# Uptake and effectiveness of a tailor-made online lifestyle advice for Dementia Risk Reduction

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Pending |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON24336

**Source**
NTR

**Brief title**
Demin

**Health condition**

dementia, Alzheimer's disease, Vascular dementia, prevention, risk reduction, lifestyle

dementie, de Ziekte van Alzheimer, vasculaire dementie, preventie, risico reductie, leefstijl

### Sponsors and support

**Primary sponsor:** University Medical Center Groningen (UMCG)
**Source(s) of monetary or material Support:** ZonMw

### Intervention

### Outcome measures

**Primary outcome**

The primary outcome is the uptake (e.g. the percentage of eligible people that signed the

online informed consent form and completed baseline risk assessment). The total number of eligible people in each recruitment group (active versus passive) will be based on the number of new cases of AD or VD (dementia patients) in all memory clinics during the recruitment period, assuming an average of one child per dementia patient. Monthly, the number of eligible participants (e.g. new cases of AD and VD) will be monitored using the medical records of each memory clinic.

**Secondary outcome**

1) The change in the dementia risk modification score. The dementia risk modification score is based on the LIBRA score, consisting of the following modifiable risk factors for dementia: alcohol consumption, coronary heart disease, physical inactivity, renal dysfunction, diabetes, high cholesterol, blood pressure, smoking, obesity, hypertension, Mediterranean diet, depression, social and cognitive activity

2) The change in the individual health behaviors over time (e.g. physical activity, diet, alcohol consumption, smoking behavior, cognitive activity and social activity)

3) Changes in beliefs and attitudes with regard to dementia risk reduction will be measured using the Motivation to Change Lifestyle and Health Behavior for Dementia Risk Reduction Scale (MCLHB-DRR scale)

4) Percentage of participants that indicated that they have followed up the tailored computerized lifestyle advice, but also the percentage of participants that indicated that they have followed up the advice to consult their General Practitioner.

# Study description

**Background summary**

Introduction: Increase in life expectancy will lead to an absolute increase in the prevalence of dementia the coming years. As no curative treatments for dementia are yet available, prevention is a key element to counteract the dementia epidemic. Having a parent with recently diagnosed dementia might encourage people to participate in a lifestyle program to get insight in their risk and protective factors for dementia and improve their health behavior. Our aim is to investigate the uptake and effectiveness of a tailor-made lifestyle program targeting risk and protective factors for dementia, consisting of an online questionnaire, physical examination at one of the participating memory clinics and online tailor-made lifestyle advice for dementia risk reduction among middle-aged descendants of people with recently diagnosed Alzheimer’s Disease (AD) or Vascular dementia (VD).

Methods and analysis: Cluster randomized controlled trial, in which memory clinics throughout the Netherlands (≥ 20) are randomized to an active or passive recruitment strategy. The difference in uptake (e.g. percentage of eligible people that completed the first assessment) between the passive (poster and flyer in waiting room of memory clinic) and active (personal invitation by the medical doctor of their parent, next to the poster and flyer) recruitment strategy will be evaluated. Additionally, the effectiveness of this tailor-made lifestyle program on protective and risk factors for dementia between participants of the program (aged 40-60 years) and a matched (using propensity scores) control group, consisting of Lifelines participants (non-exposed to the tailor-made lifestyle program) will be investigated.

Ethics and dissemination: This study is approved by the Dutch ministry of Health, Welfare and Sport according to the population screening act (see: https://www.gezondheidsraad.nl/sites/default/files/grpublication/summary_population_screening_act_study_of_online_lifestyle_advice_for_reducing_the_risk_of_dementia_201809.pdf).

## Study objective

To investigate the uptake and effectiveness of a Dementia Risk Reduction Online lifestyle Program among middle-aged descendants of people with recently diagnosed AD or VD at participating Dutch memory clinics.

## Study design

Participants are asked (by email or SMS, depending on their preference) to complete online questionnaires at 3, 6, 9 and 12 months after baseline assessment (online baseline questionnaire). After each follow up measurement, the personal health profile is updated providing the participants with new tailored computerized lifestyle advice. At baseline and 12 months follow-up, participants will be invited at the memory clinic for physical examination.

## Intervention

This study is a cluster randomized controlled trial in which participating memory clinics (≥ 20) in the Netherlands will be randomized into a passive or active recruitment strategy. Memory clinics allocated to the passive recruitment strategy, do not invite individuals actively, but individuals are invited to participate in the Dementia Risk Reduction Online Lifestyle Program only by posters and leaflets that are placed in the waiting room of the memory clinic. Memory clinics allocated to the active recruitment strategy will invite potential participants face-to-face by the medical specialist of their parent to participate in the Dementia Risk Reduction Online Lifestyle Program, during the second consultation after receiving the diagnoses AD or VD, next to posters and leaflets that are placed in the waiting room of the memory clinic. All patients (and their caregivers) receive an envelope addressed to the adult children of patients, including a standard leaflet with information about the content of the study. Participants recruited via both recruitment strategies will receive the

same Dementia Risk Reduction Online Lifestyle Program.

## Contacts

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## Eligibility criteria

### Inclusion criteria

Middle-aged adults with a parent who is recently diagnosed with Alzheimer's disease or Vascular dementia.

- Age between 40 and 60 years

- Able to use a computer

### Exclusion criteria

- Pregnant women or women were pregnant in the last 12 months

# Study design

## Design

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|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 18-12-2018 |
| Enrollment: | 378 |
| Type: | Anticipated |

## IPD sharing statement

**Plan to share IPD:** Yes

**Plan description**
This study aims to include data from 378 middle-aged participants recruited through participating memory clinics in the Netherlands. The final dataset will include data on physical examination, laboratory data from fasting blood samples and self-reported data including demographic characteristics, health and health behaviour. We will make the data and associated documentation available to users conditional on a data-sharing agreement that provides for: (1) a commitment to using the data only for research purposes, (2) a commitment to securing the data using appropriate computer technology, and (3) a commitment to destroying or returning the data after analyses are completed.

# Ethics review

Positive opinion

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|---|---|
| Date: | 21-08-2018 |
| Application type: | First submission |

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

| Register | ID |
|---|---|
| NTR-new | NL7235 |
| NTR-old | NTR7434 |
| Other | ZonMw : 531002008 ZonMw |

# Study results